

1006 Rec'd PCT/PTO 03 OCT 2005 1615

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Julie Agozino



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:
Alessandro Martini, et al.

Serial No.: 10/542,253

Confirmation No.: 5093

Filed: July 14, 2005

For: SEMI-SOLID FORMULATIONS FOR
IMMEDIATE RELEASE INTENDED FOR THE
ORAL ADMINISTRATION OF DRUGS

Group Art Unit: 1615

Examiner: Not Yet Assigned

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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97

37 CFR § 1.97(b)

- ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

37 CFR § 1.97(c)

- ☐ The Information Disclosure Statement submitted herewith is being filed after three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); after three months of the date of entry of the national stage as set forth in § 1.491 in an international application; after the mailing of a first Office Action on the merits; or after the mailing of a first Office Action after the filing of a request for continued examination under § 1.114, but before the mailing date of (1) a Final Action under § 1.113; (2) a Notice of Allowance under § 1.311; or (3) an action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the fee as set forth in § 1.17(p) to Deposit Account Number 500329.

- ☐ Applicant requests that the Examiner consider the following copending applications:

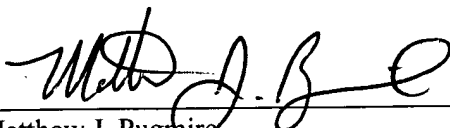
Application Serial No.	Filing Date

- ☐ Copies of these copending applications are enclosed.
- ☒ Applicant hereby requests consideration of the Information Disclosure Statement, PTO/SB/08a, submitted herewith. Copies of the cited references, except as noted below, are enclosed.
- ☐ This application is a continuation, divisional or continuation-in-part of Serial No. [REDACTED]. Copies of the cited references, if not enclosed, are available in the file of the parent application or parents thereof.
- ☒ Copies of U.S. Patents and U.S. Patent Application Publications are not enclosed. (waiver of 37 CFR 1.98(a)(2)(iii) pursuant to 37 CFR 1.183).
- ☐ Applicant hereby requests consideration of the enclosed International Search Report, which was received in a related international patent application.

The Commissioner is hereby authorized to charge any fee deficiency, including any fee required under 37 C.F.R. § 1.17(p), or credit any overpayment, to Deposit Account Number 500329. A duplicate copy of this form is enclosed.

Respectfully submitted,

Date: 9/27/05


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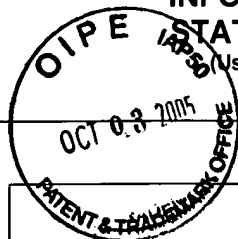
Substitute for form 1449/PTO

Complete if Known

Application Number	10/542,253
Filing Date	07-14-2005
First Named Inventor	A. Martini
Art Unit	1615
Examiner Name	TBA
Attorney Docket Number	PC27894A

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	Cite No. ¹	DOCUMENT NUMBER	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ²			
	AA	5,792,783	08-11-1998	Tang, P., et al.	
	AB	5,880,141	03-09-1999	Tang, P., et al.	
	AC	5,993,858	11-30-1999	Crison, J., et al.	
	AD	2002/0119198	08-29-2002	Gao, P., et al.	
	AE	6,514,524 B1	02-04-2003	Saslowski, O., et al.	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	AF	WO 99/61422	12-02-1999	Sugen, Inc.		
	AG	WO 98/38984	09-11-1998	Sugen, Inc.		
	AH	WO 01/30351	05-03-2001	Pharmacia & Upjohn S.P.A.		

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/542,253
Filing Date	07-14-2005
First Named Inventor	A. Martini
Art Unit	1615
Examiner Name	TBA
Attorney Docket Number	PC27894A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AI	ABDUL-FATTAH, A., et al., "Preparation And In Vitro Evaluation Of Solid dispersions Of Halofantrine," <i>International Journal Of Pharmaceutics</i> , 2002, 17-33, vol. 235.	
	AJ	AMMOURY, N., et al., "In Vitro Release Kinetic Pattern Of Indomethacin From Poly(D,L-Lactide) Nanocapsules," <i>Journal Of Pharmaceutical Sciences</i> , 1990, 763-767 vol. 79, no. 9.	
	AK	CHIOU, W., et al., "Pharmaceutical Applications Of solid Dispersion Systems," <i>Journal Of Pharmaceutical Sciences</i> , 1971, 1281-1302, vol. 60, no. 9.	
	AL	DORDUNOO, S., et al., "Preformulation Studies On Solid Dispersions Containing Triamterene Or Temazepam In Polyethylene Glycols Or Gelucire 44/14 For Liquid Filling Of Hard Gelatin Capsules," <i>Drug Development And Industrial Pharmacy</i> , 1991, 1685-1713, vol. 17, no. 12.	
	AM	KHOO, et al., "The Formulation Of Halofantrine As Either Non-Solubilising PEG 6000 Or Solubilising Lipid Based Solid Dispersions: Physical Stability And Absolute Bioavailability Assessment," <i>International Journal Of Pharmaceutics</i> , 2000, 65-78, vol. 205.	
	AN	SAN VICENTE, A., et al., "Influence Of Ageing On The Release Of Salbutamol Sulphate From Capsules Elaborated With Gelucire 35/10, 48/09 And 46/07," <i>Proceedings of the 2nd World Meeting APGI/APV</i> , Paris 1998, 261-262,	
	AO	SERAJUDDIN, A., et al., "Solid Dispersion Of Poorly Water-Soluble Drugs: Early Promises Subsequent Problems, And Recent Breakthroughs," <i>Journal Of Pharmaceutical Sciences</i> , 1999, 1058-1066, vol. 88, no. 10	
	AP	SHEEN, P., et al., "Formulation Studies Of A Poorly Water-Soluble Drug In Solid Dispersions To Improve Bioavailability," <i>International Journal Of Pharmaceutics</i> , 1995, 221-227, vol. 118.	
	AQ	SUTANANTA, W., et al., The Effects Of Ageing On The Thermal Behaviour And Mechanical Properties Of Pharmaceutical Glycerides," <i>International Journal Of Pharmaceutics</i> , 1994, 51-62, vol. 111.	

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